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18M2/1103

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2787

**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

- ☐ Note attached communication from the Examiner  
☐ This notice is issued in view of applicant's communication filed \_\_\_\_\_

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/400,179	03/06/95	031	MARTINELL, J	1804 11/03/95
First Named Applicant	SUGANO	HARUO		

TITLE OF INVENTION  
NOVEL DNA AND RECOMBINANT PLASMID

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 1123971-303	435-172.300	075	UTILITY	NO	\$1250.00	02/05/96

**THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

**I. Review the SMALL ENTITY Status shown above.**

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or  
B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or  
B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

**II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.**

**III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.**

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/400,179 03/06/95 SUGANO

H 1123971-303

18M2/1103

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2787

EXAMINER	
MARTINELL, J	
ART UNIT	PAPER NUMBER
	29/F

DATE MAILED: 1804

11/03/95

NOTICE OF ALLOWABILITY

PART I.

- ☒ This communication is responsive to the amendment filed 09/25/95.
- ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- ☒ The allowed claims are 10-15, 30-49, 51, 52, and 55-57.
- ☒ The drawings filed on 06/18/82 is acceptable.
- ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received. ☐ not been received. ☐ been filed in parent application Serial No. 06/201355, filed on 10/27/80.
- ☒ Note the attached Examiner's Amendment.
- ☒ Note the attached Examiner Interview Summary Record, PTOL-413.
- ☒ Note the attached Examiner's Statement of Reasons for Allowance.
- ☒ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No.                     . CORRECTION IS REQUIRED.
  - ☐ The proposed drawing correction filed on                      has been approved by the examiner. CORRECTION IS REQUIRED.
  - ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☒ Examiner's Amendment
- ☒ Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☐ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

Serial No. 08/400,179

Art Unit 1804

An extension of time under 37 C.F.R. § 1.136(a) is required in order to make an Examiner's Amendment which places this application in condition for allowance. During a telephone conversation conducted on October 12, 1995, Mr. Lippert requested an extension of time for ONE month(s) and authorized the Commissioner to charge Deposit Account No. 23-1703 the required fee of \$ 110.00 for this extension and authorized the following Examiner's Amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Lippert on October 12, 1995.

Cancel claims 60-62.

The following is an Examiner's Statement of Reasons for Allowance:

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A copy of the Bethesda Research Laboratory Catalog of 1979 and the article by Fernandez et al (FEBS Lett. 87: 277 (1978)) are included in the file as evidence of the availability of plasmids pBR322, pMB9, and pCR1.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 308-4312. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

  
JAMES MARTINELL, PH.D.  
SENIOR LEVEL EXAMINER  
GROUP 1800

Claims 53, 54, 58, and 59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

Claims 53, 54, 58, and 59 are drawn to polypeptides and are classified in Class 530, subclass 351. The inventions are distinct, each from the other because of the following reasons. The proteins of claims 53, 54, 58, and 59 are materially different from and are therefore separate and distinct from the plasmids and host cells of claims 10-15, 30-37, 49-51, 55, and 56. The processes for producing plasmids and transformed host cells of claims 38-48 are not needed to produce the proteins of claims 53, 54, 58, and 59, which proteins can be purified from naturally occurring sources or may be synthesized chemically. Additionally, the processes of claims 38-48 can be used for purposes other than the production of the proteins of claims 53, 54, 58, and 59, for example, the production of large amounts of sequence specific nucleic acids. Finally, the methods of claims 52 and 57 are not needed to produce the proteins of claims 53, 54, 58, and 59 because said proteins may be purified from naturally occurring sources or may be synthesized chemically.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53, 54, 58, and 59 withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

The disclosure is objected to because of the following informalities. A typographical error occurs in the sequences of claims 31, 55, 56, and 57. In each of the claims in line 4 of each sequence, "CAT" should be changed to "GAT" (compare to Table 5, position 9 of the mature sequence). Appropriate correction is required.

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Art Unit 1804

Claims 49-52 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to processes and host cells in which expression is shown. See M.P.E.P. §§ 706.03(n) and 706.03(z). The instant application does not enable the expression of  $\beta_1$  interferon in any and all hosts or any and all host cells. Applicants' arguments (paper no. 22, page 11 and Exhibit B) are not convincing because the host cells used are not mentioned. This is not an invitation to submit further evidence subsequent to a final Office action.

Claims 49 and 50 are each rejected over the other as being substantial duplicate claims. No difference is seen between the claims.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. It is not evident that each of the plasmids and microorganisms mentioned in claims 10, 15, 36, 37, 42, 43, and 48 is permanently available to the public. A "Suggestion for the Deposit of Biological Material" is attached to this Office action. This attachment was inadvertently not attached to the Office action mailed January 14, 1994. The error is regretted. This objection and the following rejection are repeated for reasons already of record (e.g., Office action mailed January 14, 1994, page 2). Applicants' arguments (paper no. 22, pages 8-9) are not convincing. First, a catalog from 1991 cannot be used as evidence of availability for plasmids in the instant application because the effective filing date of the instant application extends to 1980. Second, applicants' assurance to provide availability for the term of any patent that issues on the instant application is inadequate to overcome the objection and rejection because availability is to be

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assured for the enforceable life of the patent, not the term of the patent (e.g., see Office action mailed January 14, 1994).

Claims 10, 15, 36, 37, 42, 43, and 48 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 11-14, 30-35, 38-41, and 44-47 are allowable over the prior art of record.

This is a Continuation Application of applicant's earlier application S.N. 06/389,922. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 308-4312. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

Serial No. 08/400,179

Art Unit 1804

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1804.



JAMES MARTINELL, PH.D.  
SENIOR LEVEL EXAMINER  
GROUP 1800